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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,655

02/12/2007

Adam Siddiqui-Jain

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25225 7590 10/22/2008

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

10/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,655	<b>Applicant(s)</b> SIDDIQUI-JAIN ET AL.	
	<b>Examiner</b> Ethan Whisenant, Ph.D.	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 APR 06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/2006 and 4/21/2008</u> . | 6) <input type="checkbox"/> Other: ____.  |

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**NON-FINAL ACTION**

1. **Claim(s) 1-25** as originally filed 14 APR 07 pending in this application.

**SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

**35 U.S.C. 112 1ST PARAGRAPH**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH**

4. **Claim(s) 21-25** is/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to identify a quadruplex interacting molecule, does not reasonably provide enablement for the treatment (i.e. ameliorating) all cellular proliferative disorders or the treatment of all viral infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary;

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(b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, the breadth of the claims, encompass the treatment of all cellular proliferative disorders and all viral infections.

The specification provides no working examples of any compounds isolated using the claimed method which can be used to treat any and every type of cellular proliferative disorders and any and every type of viral infection.

The quantity of experimentation necessary to confirm that any of compounds identified can be used to treat any and all cellular proliferative disorders and any and all viral infections will require years of research.

Finally, the state of the prior art makes clear that once a lead drug is discovered it then requires extensive research (i.e. multiple year) to determine the clinical suitability of the drug identified and/or derivatives thereof. In support of this position see the information found on the internet at:

<http://www.montrealinternational.com/sciences/drug/introduction.html>

which describes in simple terms the process of drug discovery.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

**5. Claim(s) 1-25** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1** is indefinite because the phrase “a candidate molecule” lacks proper antecedent basis. **Claim 1** is also indefinite because there is no nexus between the preamble and the claim steps. Claim 1 in its preamble directs to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

**CONCLUSION**

**6. Claim(s)1-25** is/are rejected and/or objected to for the reason(s) set forth above.

**7.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/  
Primary Examiner  
Art Unit 1634

## **EXAMINER SEARCH NOTES**

**17 OCT 08 - ECW**

**Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &**

**CAplus, Medline and BIOSIS via STN**

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Siddiqui-Jain A?/au

Quadruplex

G –quadruplex

G4 DNA

Screening method

Identification or identify

Test (molecule or compound)

Competition or competitor